| 1 | BILL LOCKYER, Attorney General | | |
|----|--|---|--|
| 2 | of the State of California KIM M. SETTLES, State Bar No. 116945 | | |
| 3 | Deputy Attorney General California Department of Justice | | |
| 4 | 1515 Clay Street, 20 th Floor P.O. Box 70550 | | |
| 5 | Oakland, CA 94612-0550 Telephone: (510) 622-2138 | | |
| 6 | Facsimile: (510) 622-2270 | | |
| 7 | Attorneys for Complainant | | |
| 8 | BEFORE THE BOARD OF PHARMACY | | |
| 9 | DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA | | |
| 10 | | | |
| 11 | In the Matter of the Accusation Against: | Case No. 2686 | |
| 12 | ELMHURST PHARMACY 7400 MacArthur Boulevard | OAH No. N2005020735 | |
| 13 | Oakland, CA 94605 Pharmacy License No. PHY 45683 | | |
| 14 | PARAGI PATEL | STIPULATION IN SETTLEMENT | |
| 15 | 16897 Robey Drive San Leandro, CA 94578 Registered Pharmacist License No. RPH 49421 | [AS TO RESPONDENT MICHAEL HALL ONLY] | |
| 16 | and | • | |
| 17 | MICHAEL HALL | | |
| 18 | 584 Castro Street, No. 423 San Francisco, CA 94114 | | |
| 19 | Registered Pharmacist License No. RPH 46426 | | |
| 20 | Respondents. | | |
| 21 | | · | |
| 22 | IT IS HEREBY STIPULATED by and between MICHAEL HALL, a respondent | | |
| 23 | in this proceeding, by and through his attorney Mark Epstein, and the Board of Pharmacy, | | |
| 24 | Department of Consumer Affairs, State of California, by and through its attorney, Kim M. | | |
| 25 | Settles, Deputy Attorney General, that: | | |
| 26 | 1. The accusation in case number 2686 is currently pending against | | |
| 27 | MICHAEL HALL ("respondent"), said accusation having been filed with the Board of Pharmacy, | | |
| 28 | Department of Consumer Affairs, State of Californi | a ("Board"). | |
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- 2. Patricia F. Harris, Executive Officer of the Board, is the complainant in the accusation, which was filed in her official capacity.
- 3. Respondent, MICHAEL HALL is represented by Mark Epstein, of The Epstein Group, in this matter.
- 4. Respondent has fully considered the charges and allegations contained in the Accusation No. 2686 on file with the Board of Pharmacy, Department of Consumer Affairs.
- 5. Respondent is fully aware of his right to a hearing on the allegations contained in the accusation, his right to confront and cross-examine witnesses against him, his right to reconsideration, appeal, and any and all other rights which may be accorded him under the California Administrative Procedure Act (Government Code, § 11500 et seq.) and, with this in mind, freely and voluntarily waives such rights.
- 6. Respondent admits the truth of each and every allegation contained in the sixth and seventh causes of discipline as set forth in the Accusation on file herein (attached hereto as Attachment A), with the exception that page 7, line 21 of paragraph 37 should read, "was supervising two (2) pharmacy technicians and one (1) pharmacy clerk," and stipulates that, accordingly, cause for discipline exists against his license, as set forth in the Accusation.
- 7. It is acknowledged by the parties that this stipulation constitutes an offer in settlement to the Board of Pharmacy and is not effective until adoption by the Board.
- 8. In the event this stipulation is not adopted by the Board, nothing herein recited shall be construed as a waiver of respondent's right to a hearing or as an admission of the truth of any of the matters contained in the accusation.
- 9. Respondent understands that in signing this stipulation rather than contesting the accusation, he is enabling the Board to issue the following order without further legal process.
- 10. Based upon the foregoing recitals, THE PARTIES STIPULATE AND AGREE THAT the Board of Pharmacy shall, without further notice or formal proceeding, issue the following order:

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<u>ORDER</u>

IT IS HEREBY ORDERED that Accusation No. 2686 is withdrawn as to MICHAEL HALL; however, a Citation, with a \$250.00 administrative fine, shall be deemed to be issued to MICHAEL HALL, as of the effective date of this Stipulated Settlement, with regard to violations of Business and Professions Code sections 4116 (a) and 4115(g), as described in the sixth and seventh causes for discipline contained in the accusation. The following terms and conditions shall apply:

- a. The administrative fine shall be due 30 days from the effective date of this Stipulated Settlement.
- b. Respondent MICHAEL HALL agrees to comply with and not to contest the citation; in the event that respondent fails to comply with the citation, such noncompliance may result in disciplinary action by the Board.

ACCEPTANCE

I have carefully read the Stipulated Settlement and Disciplinary Order. I understand the stipulation and the effect it will have on my Registered Pharmacist License No. RPH 46426. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3-22-05

MICHAEL HX Respondent

I have read and fully discussed with respondent MICHAEL HALL, the terms and conditions and the other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: March 22, 2005

Attorney for Respondent

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. DATED: __3/22/05 BILL LOCKYER, Attorney General of the State of California Kim M. Settles KIM M. SETTLES Deputy Attorney General Attorneys for Complainant

90018344.wpd

DOJ Docket/Matter ID Number: 03583110-SF2003400447

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

| ELMHURST PHARMACY | | |
|--------------------------|---|--|
| 7400 MacArthur Boulevard | | |
| 0 11 1 04 04005 | • | |

In the Matter of the Accusation Against:

Oakland, CA 94605 Pharmacy License No. PHY 45683

PARAGI PATEL 16897 Robey Drive San Leandro, CA 94578 Registered Pharmacist License No. RPH 49421

and

MICHAEL HALL 584 Castro Street, No. 423 San Francisco, CA 94114 Registered Pharmacist License No. RPH 46426

Respondents.

Case No. 2686

OAH No. N2005020735

[AS TO RESPONDENT MICHAEL HALL ONLY]

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

| This Decision shall l | become effe | ctive on | July 20, | 2005 | |
|-----------------------|-------------|----------|----------|------|--|
| It is so ORDERED | June 20 | 2005 | • | | |

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

WILLIAM POWERS Board Vice President

Exhibit A
Accusation No. 2686

| 1 | BILL LOCKYER, Attorney General | |
|-----|--|--|
| | of the State of California | |
| 2 | FRED A. SLIMP II, State Bar No. 118693 | |
| 3 | Deputy Attorney General California Department of Justice | |
| | 1515 Clay Street, 20th Floor ~ P.O. Box 70550 | |
| 4 | Oakland, CA 94612-0550 | |
| 5 | Telephone: (510) 622-2117 Facsimile: (510) 622-2121 | |
| 6, | Attorneys for Complainant | |
| 7 | | |
| 8 | BEFORE T | |
| | BOARD OF PHA DEPARTMENT OF CON | ARMACY ISTIMER AFFATRS |
| 9 | STATE OF CAL | IFORNIA |
| 10 | | |
| 11 | In the Matter of the Accusation Against: | Case No. 2686 |
| 12 | ELMHURST PHARMACY | ACCUSATION |
| - 1 | 7400 MacArthur Boulevard | |
| 13 | Oakland, CA 94605 | |
| 14 | Pharmacy License No. PHY 45683, | |
| 15 | PARAGI PATEL | |
| 16 | 16897 Robey Drive San Leandro, CA 94578 | |
| 16 | | |
| 17 | Registered Pharmacist License No. RPH 49421, | |
| 18 | and | |
| 19 | MICHAEL HALL | |
| | 584 Castro Street, No. 423 | |
| 20 | San Francisco, CA 94114 | |
| 21 | Registered Pharmacist License No. RPH 46426, | |
| 22 | Respondents. | |
| 23 | | |
| 24 | Complainant alleges: | |
| 25 | <u>PARTII</u> | <u>ES</u> |
| 26 | l. " | ngs this Accusation solely in her official |
| 27 | capacity as the Executive Officer of the Board of Pl | harmacy, Department of Consumer Affairs. |
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| /.X | H /// | • |

- 2. On or about February 7, 2002, the Board of Pharmacy issued Pharmacy License Number PHY 45683 to Elmhurst Pharmacy (respondent Pharmacy or Elmhurst). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2004, unless renewed.
- 3. On or about May 1, 1997, the Board of Pharmacy issued Registered Pharmacist License Number RPH 49421 to Paragi Patel (respondent Patel or Patel). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2005, unless renewed. Respondent Patel was the designated pharmacist-in-charge at respondent Pharmacy at all times relevant to the charges brought herein.
- 4. On or about August 13, 1993, the Board of Pharmacy issued Registered Pharmacist License Number RPH 46426 to Michael Hall (respondent Hall or Hall). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2004, unless renewed.

<u>JURISDICTION</u>

- 5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 6. Section 4301(f) of the Code provides in pertinent part that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to, the commission of any act involving dishonesty, whether the act is committed in the course of relations as a licensee or otherwise.
- 7. Section 4301(g) of the Code provides in pertinent part that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to, knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- 8. Section 4301(j) of the Code provides in pertinent part that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to the violation of any of the statutes of this state or of the United States

regulating controlled substances and dangerous drugs.

- 9. Section 4301(o) of the Code provides in pertinent part that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to, violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.
- 10. Section 4022 of the Code provides in pertinent part that "dangerous drug" means any drug unsafe for self-use of any other drug that by federal or state law can be lawfully dispensed only on prescription.
- 11. Section 4081(a) of the Code provides in pertinent part that all records of manufacture and of sale, acquisition, or disposition of dangerous drugs shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making.
- 12. Section 4113(a) of the Code provides in pertinent part that every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the Board in writing of the identity and license number of that pharmacist and the date he or she was designated.
- 13. Section 4113(b) of the Code provides in pertinent part that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
- 14. Section 4113(c) of the Code provides in pertinent part that every pharmacy shall notify the Board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge.
- 15. Section 4115(f) of the Code provides in pertinent part that the performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist, that the pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician, that a pharmacy technician may perform specified permissible duties only under the immediate, personal supervision and control of a pharmacist, that any pharmacist responsible for

a pharmacy technician shall be on the premises at all times, and that the pharmacy technician shall be within the pharmacist's view.

- 16. Section 4115(g) of the Code provides in pertinent part that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing specified permissible tasks, and that the ratio of pharmacy technicians performing specified permissible tasks to any additional pharmacist shall not exceed 2:1.
- 17. Section 4116(a) of the Code provides in pertinent part that no person other than a pharmacist, intern pharmacist, authorized law officer, or person authorized to prescribe shall be permitted in that area, place, or premises wherein controlled substances or dangerous drugs are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
- 18. Section 111255 of the Health & Safety Code provides in pertinent part that any drug is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
- 19. Section 111295 of the Health & Safety Code provides in pertinent part that it is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug that is adulterated.
- 20. Title 16, California Code of Regulations, section 1714(d) ("16 CCR § 1714(d)") provides in pertinent part that each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs or devices, and records for such drugs and devices.
- 21. Section 125.3 of the Code states in pertinent part that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUGS

22. Seroquel, a trade name for the chemical compound quetiapine fumarate, is an oral medication for the treatment of schizophrenia in adults and a dangerous drug within the meaning of Code section 4022.

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23. Respondents Elmhurst Pharmacy, Paragi Patel and Michael Hall are guilty of unprofessional conduct as more particularly set forth herein below.

Respondents Pharmacy and Patel

FIRST CAUSE FOR DISCIPLINE

(Dishonesty)

(Bus. & Prof. Code § 4301(f))

- 24. Between April 1, 2002, and June 30, 2002, on multiple occasions the dates of which are known to respondents Pharmacy and Patel, but unknown to complainant, respondents Pharmacy and Patel rebilled, and thereby overbilled, Medi-Cal in the amount of \$23,878.40 for prescriptions of the dangerous drug Seroquel previously delivered to physician W. S.¹ which were returned to respondents and subsequently reused and sold again and redelivered to physician W. S. for distribution to other patients, without credit to Medi-Cal therefor.
- 25. The conduct of respondents Pharmacy and Patel set forth in paragraph 24, above, constitutes dishonesty and therefore unprofessional conduct within the meaning of Code section 4301(f).

SECOND CAUSE FOR DISCIPLINE (Making of Document with Misrepresentation)

(Bus. & Prof. Code § 4301(g))

- 26. Complainant realleges paragraph 24, above, and incorporates it herein by reference as if fully set forth at this point.
- 27. In conjunction with the rebilling for prescriptions of used Seroquel previously delivered to physician W. S. as set forth in paragraph 24, above, respondents Pharmacy and Patel executed Medi-Cal reimbursement claims that falsely represented the status of the Seroquel rebilled for as not previously used, delivered or billed for.
- 28. The conduct of respondents Pharmacy and Patel set forth in paragraph 27, above, constitutes the knowing making of documents that falsely represent the existence of facts and therefore unprofessional conduct within the meaning of Code section 4301(g).

^{1.} The full names of all persons referred to herein will be made available to respondents upon a request for discovery.

THIRD CAUSE FOR DISCIPLINE

(Violation of Drug Statutes) (Bus. & Prof. Code § 4301(j))

- 29. Complainant realleges paragraph 24, above, and incorporates it herein by reference as if fully set forth at this point.
- 30. In conjunction with the redelivery of used Seroquel as set forth in paragraph 24, above, respondents Pharmacy and Patel held, offered for sale, sold and delivered said dangerous drug previously held by physician W. S. under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
- 31. The conduct of respondents Pharmacy and Patel set forth in paragraph 30, above, constitutes a violation of Health & Safety Code section 111295 and therefore unprofessional conduct within the meaning of Code section 4301(j).

FOURTH CAUSE FOR DISCIPLINE (Failure to Maintain Records)

(Bus. & Prof. Code § 4081(a), 4301(j))

- 32. On or about February 9, 2002, February 20, 2002, March 4, 2002, and August 9, 2002, respondents Pharmacy and Patel made five (5) payments for shipments of dangerous drugs received from drug supplier "Hwave" in the amounts of \$4,935.15, \$16,533.51, \$19,124.56, \$6,391.00, and \$6,500.00. Respondents Pharmacy and Patel failed to produce invoices from supplier "Hwave" corresponding to the above payments when requested to do so by a Board inspector on February 27, 2003.
- 33. The conduct of respondents Pharmacy and Patel in failing to maintain and produce invoices for shipments of dangerous drugs from supplier "Hwave" when requested to do so on February 27, 2003, constitutes violation of Code section 4081(a) and therefore unprofessional conduct within the meaning of Code section 4301(j).

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FIFTH CAUSE FOR DISCIPLINE (Technicians Not Subject to Visual Supervision) (Bus. & Prof. Code § 4115(f))

- 34. On or about February 27, 2003, inspector Ralph. S. Orlandella, Pharm.D., (Orlandella) inspected the premises of respondent pharmacy. Orlandella observed that respondent pharmacy maintained a nursing home dispensing area within the pharmacy proper but outside the restricted licensed area. Controlled substances and dangerous drugs were maintained and/or prepared and/or packaged for dispensing in the nursing home dispensing area. The said nursing home dispensing area lacks a window or other means for a pharmacist to maintain visual supervision of persons performing tasks within the nursing home dispensing area.
- 35. The conduct of respondents Pharmacy and Patel in maintaining the nursing home dispensing area without providing for direct visual supervision by a pharmacist of activities performed therein constitutes a violation of Code section 4115(f) and therefore unprofessional conduct within the meaning of Code sections 4301(o) (violation of chapter).

Respondents Pharmacy, Patel and Hall

SIXTH CAUSE FOR DISCIPLINE (Improper Pharmacist/Technician Ratio) (Bus. & Prof. Code § 4115(g))

- 36. Complainant realleges paragraph 34, above, and incorporates it herein by reference as if fully set forth at this point.
- 37. Orlandella also observed during his inspection of respondent Pharmacy on February 27, 2003 that respondent Hall was the only pharmacist on duty and that respondent Hall was supervising five (5) pharmacy technicians and one (1) pharmacy clerk.
- 38. The conduct of respondents Pharmacy, Patel and Hall in allowing respondent Hall to supervise five (5) pharmacy technicians as set forth in paragraph 37, above, constitutes a violation of Code section 4115(g) and therefore unprofessional conduct within the meaning of Code section 4301(o) (violation of chapter).

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SEVENTH CAUSE FOR DISCIPLINE (Nonpharmacists in Secure Area without Pharmacist Present) (Bus. & Prof. Code § 4116(a))

- 39. Complainant realleges paragraph 34, above, and incorporates it herein by reference as if fully set forth at this point.
- 40. Orlandella also observed during his inspection of respondent pharmacy on February 27, 2003, that three (3) non-professional staff members were present in the nursing home dispensing area without a pharmacist being present at the same time.
- 41. The conduct of respondents Pharmacy, Patel and Hall in permitting unauthorized non-professional staff to be in an area, place, or premises wherein controlled substances or dangerous drugs are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged without a pharmacist being present as set forth in paragraph 40, above, constitutes a violation of Code section 4116(a) and therefore unprofessional conduct within the meaning of Code section 4301(o) (violation of chapter).

EIGHTH CAUSE FOR DISCIPLINE (Violation of Drug Regulation) (16 CCR § 1714(d), Bus. & Prof. Code § 4301(o))

- 42. Complainant realleges paragraph 34, above, and incorporates it herein by reference as if fully set forth at this point.
- 43. The said nursing home dispensing area is a large auditorium-size area with an entrance doorway separate from the entrances to the pharmacy and the licensed area and also contains a fire exit at its rear. During his inspection of respondent pharmacy on February 27, 2003, Orlandella also noted that the separate doorway to the nursing home dispensing area was allowed to remain unlocked and that controlled substances or other dangerous drugs or devices were removable via the fire exit without observation by pharmacist staff, thus placing controlled substances and/or dangerous drugs or devices in an unsecured condition with high risk of theft.
- 44. The conduct of respondents Pharmacy, Patel and Hall in failing to secure the nursing home dispensing area and creating a high risk of theft thereby constitutes a violation of 16 CCR § 1714(d) and therefore unprofessional conduct within the meaning of Code section 4301(o) (violation of Board regulations).

46. The conduct of respondents Pharmacy, Patel and Hall in failing to provide the Board with required notice as set forth in paragraph 45, above, constitutes violation of Code sections 4113(a) or 4113(c) and therefore unprofessional conduct within the meaning of Code section 4301(o) (violation of chapter).

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PRAYER

| WHEREFORE, Complainant requests that a hearing be held on the matters | herein |
|--|--------|
| alleged and that, following the hearing, the Board of Pharmacy issue a decision: | |

- 1. Revoking or suspending Pharmacy License Number PHY 45683 issued to Elmhurst Pharmacy;
- 2. Revoking or suspending Registered Pharmacist License Number RPH 49421 issued to Paragi Patel;
- 3. Revoking or suspending Registered Pharmacist License Number RPH 46426 issued to Michael Hall;
- 4. Ordering Elmhurst Pharmacy, Paragi Patel and Michael Hall to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case pursuant to Code section 125.3; and
 - 5. Taking such other and further action as may be deemed necessary or proper.

DATED: 11/6/03

PATRICIA F. HARRIS

Executive Officer

Roard of Pharmacy

Board of Pharmacy Department of Consumer Affairs

State of California

Complainant